

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; Section 502 (e) (1), the repackaged tablets failed to bear a label containing the common or usual name of the drug; and, Section 502 (f) (2), they bore no labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: August 17, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$300.

3208. Misbranding of methyl testosterone tablets and alpha estradiol tablets.
U. S. v. Norman N. Beil (Research Products). Plea of guilty. Fine of \$800, plus costs. (F. D. C. No. 28120. Sample Nos. 2780-K, 3779-K, 12349-K, 24998-K.)

INFORMATION FILED: January 25, 1950, Northern District of Ohio, against Norman N. Beil, trading as Research Products, Cleveland, Ohio.

ALLEGED SHIPMENT: On or about January 27, 28, and 31, and February 10, 1949, from the State of Ohio into the States of Maryland, Virginia, Delaware, and South Dakota.

LABEL, IN PART: (Methyl testosterone tablets). "Male Hormone Tablets Each Tablet Contains 10 mg. [or "5 mg."] Methyl Testosterone For use when Methyl Testosterone is indicated for symptoms of Male Hormone Deficiency. Suggested Average Dose: One (1) tablet daily when the use of male hormones is directed by your physician. Warning: The male sex hormone should not be used if there is any indication of cancer of the prostate."

Accompanying 2 of the 3 shipments of *methyl testosterone tablets* were circulars entitled "The Male Hormone," and one of these shipments also was accompanied by an instruction sheet entitled "Important Instructions." The label of the *alpha estradiol tablets* (female hormones) had been destroyed by the consignee, but the consignment was accompanied by a copy of the circular entitled "The Male Hormone," which contained certain representations regarding the female hormone.

NATURE OF CHARGE: *Methyl testosterone tablets.* Misbranding, Section 502 (a), (2 shipments) certain statements in the labeling were false and misleading. The labeling represented and suggested that the article would stimulate growth and development of the sex organs and the male sex characteristics, such as distribution of hair, muscular development, and depth of voice; that it would correct lack of sexual power and impotence; that it would relieve and postpone the many conditions associated with middle age, and would improve the sense of well-being; that it constituted for the average man in his late forties an adequate treatment for flushes, sweats, chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression and general weakness, and poor physical strength; that the use of the article would result in improved physical and mental work, and would exert a tonic action resulting in renewed vigor; and that the article would impart a better attitude toward social life, and would cause nervousness, exhaustion, and melancholy to disappear. The article would not be effective for such purposes. Further misbranding, Section 502 (f) (1), (all shipments) the labeling failed to bear adequate directions for use in that the directions for use appearing in the labeling were inadequate.

Further misbranding, Section 502(f) (2), (2 shipments) the labeling failed to bear adequate warnings against use in those pathological conditions where the use of the article may be dangerous to health, and against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users since each tablet contained 10 milligrams of methyl testosterone; and the labeling of the article failed to bear adequate warnings against use by individuals who may have cancer of the prostate since the ordinary lay user is not familiar with the indications of cancer of the prostate.

Alpha estradiol tablets. Misbranding, Section 502(a), certain statements in the labeling, i. e., in the accompanying circular entitled "The Male Hormone," were false and misleading. The labeling represented and suggested that the article would relieve and postpone the many conditions associated with middle age, and that the article constituted an adequate treatment for hot flashes, emotional disturbances and other manifestations associated with the menopause. The article would not be effective for such purposes.

DISPOSITION: March 24, 1950. A plea of guilty having been entered, the court fined the defendant \$800, plus costs.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3209. Adulteration and misbranding of adhesive bandages. U. S. v. 180 Cartons, etc. (and 2 other seizure actions). (F. D. C. Nos. 28995, 29235, 29272. Sample Nos. 46598-K, 46599-K, 47244-K, 47245-K, 47547-K.)

LIBELS FILED: April 25, May 19, and June 14, 1950, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 2, April 17, and May 1, 1950, by the Seamless Rubber Co., from New Haven, Conn.

PRODUCT: Adhesive bandages. 540 cartons, each containing 12 tins, 23 boxes, each containing 720 tins, and 780 cartons, each containing 12 tins, at Pittsburgh, Pa.

LABEL IN PART: "Quik-Bands Assorted Sterilized, Plain [or "Quik-Bands Assorted with Mercurochrome * * * Sterilized"] * * * Adhesive Bandages" and "Rexall First Aid Quik-Bands Adhesive Bandages."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was not sterile.

Misbranding, Section 502 (a), the label statements "Sterile," "First Aid," and "Sterilized" were false and misleading as applied to an article that was not sterile.

DISPOSITION: July 21 and August 4, 1950. The Seamless Rubber Co. having appeared as claimant for the lot of 540 cartons and the lot of 23 boxes and consented to the entry of decrees, judgments of condemnation were entered and the court ordered that such lots be released under bond to be brought into compliance with the law by resterilization. In the matter of the lot of 780 cartons, only 60 cartons were on hand at the time of seizure. No claimant

*See also No. 3201.